



State of Washington
DEPARTMENT OF FISH AND WILDLIFE

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November 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on docket number 99D-2638 'Use of Medicated Feeds for Minor Species';
Draft Compliance Policy Guide.

The State of Washington, Department of Fish and Wildlife, would like to comment regarding proposed changes in FDA policy to increase access to extra-label use of drugs in minor use species. Lack of new animal drugs to treat disease is a major problem to the aquaculture industry. The State of Washington has one of the largest aquaculture programs in the nation. Often in the operation of state facilities, in spite of stringent preventive measures, disease events occur. Entire year classes of fish stocks can be lost. Knowing treatments exist to stop this loss, but these therapies cannot legally be accessed, demonstrates the need for change in current policies. The state welcomes and fully supports the steps taken by the Food and Drug Administration (FDA) in writing the Compliance Policy Guide "Use of Medicated Feeds for Minor Species" (99D-2638). The Animal Medicinal Drug Use Clarification Act (AMDUCA) was a positive step for most specialties of veterinary medicine but aquaculture was left behind due to restrictions on the use of extra-label drugs in and on feeds. This document represents a major step forward for the aquaculture industry and for all minor use species.

It is the understanding of the state that 99D-2638 would allow an existing medicated feed to be used in an extra label fashion. A medicated feed designed for another species like swine or poultry could potentially be used in fish. Medicated feeds manufactured for fish could be used at extra label doses, for other than labeled diseases, and on other than labeled fish species. While this certainly provides opportunities, there are some drawbacks. There are only two approved antibiotics for use in salmonids. Feeds for other fish species or animals may not be accepted by salmonids and/or may be detrimental to their health. Following are some suggestions that if implemented, would make 99D-2638 even more valuable and useful for the treatment of minor use species.

The goal of AMDUCA, and the intent of the U.S. Congress when drafting this law, was to provide relief of pain and suffering for diseased animals and to allow veterinarians access to drugs or treatments that would not otherwise be labeled or available for a given species due to cost of the labeling process. The prohibition of extra label drug use in and on feeds effectively took AMDUCA away from aquaculture since fish cannot practically be medicated in any other fashion than through oral presentation of the drug. In a joint conference with the American Veterinary Medical Association (AVMA) and FDA in February 1997 to explain

99D-2638

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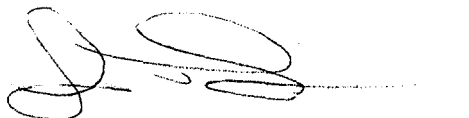
AMDUCA, Dr. Stephen Sundlof stated that the major reasons medicated feeds were not included under AMDUCA were objections from feed companies regarding record keeping, disruption of distribution, and liability issues. This statement is published in the AVMA Journal. Veterinarians are permitted to use extra-label drugs in feeds for species other than fish, if that use does not involve a feed company, for example, adding antibiotics to milk fed to calves in the dairy industry. This was also published in the AVMA Journal. The state proposes 99D-2638 be expanded to allow antibiotics to be added to feed at the point of use or at the hatchery facility. This method of delivery historically has proven quite effective in the treatment of fish disease, and would not involve a feed company. It would provide the opportunity to use extra label application of any food animal antibiotic to a feed that is designed for the animal being treated, in this case fish. Applying antibiotics to fish feeds at the hatchery facility would avoid any nutritional problems and acceptance issues created by using a feed designed for another animal. It would avoid dispensing improper drug doses as feeds designed for swine or poultry may have too high of a drug dose for a fish that is a fraction of the weight of the intended animal. It would alleviate pain and suffering of the diseased fish, which was the purpose of AMDUCA. If the intent of the FDA and 99D-2638 is to allow extra-label use of antibiotics in minor species as intended by AMDUCA, then it follows that top-dressing antibiotics onto feeds specifically designed for that minor use species would be a more logical step than using a feed that is not designed for use in that animal and could be potentially hazardous. While we applaud the action the FDA is taking with 99D-2638, if the FDA truly wants to help the aquaculture industry they should strongly consider taking this next step.

The fish raised by the Washington Department of Fish and Wildlife Hatchery Program is an important asset to the state and to the nation. Sport fishing generates billions of dollars in revenue to local economies throughout the U.S. Washington State hatchery's bolster the returns of many endangered salmonid populations and in many cases our hatcheries contain the only remaining genetically indigenous fish stocks available for restoration. This is an important issue, please give thoughtful consideration to our comments. The future of this industry depends upon the ability to access chemotherapeutics when needed as can be done in other countries such as Canada and the European Community. The U.S. currently lags far behind the aquaculture industry of these other countries in many ways, but especially when it comes to the availability of drugs. 99D-2368 is a step in the right direction in addressing the problems of aquaculture but in our opinion it does not go far enough. Thank you for this opportunity to express our comments and suggestions. Please feel free to contact us for further clarification.

Sincerely,

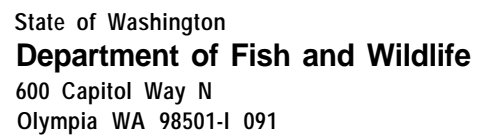


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Dr. Jed Varney, DVM
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cc: Dr. Jeff Koenings, Larry Peck, Lew Atkins, Gene Tillett

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